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K081403

BIONOSTICS
Quality Solutions

510(k) Summary[2]

JUL 25 2008

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Contact Person

Randy Byrd
VP, Chief Technical Officer
(978) 772-7070 x 272

Date of preparation of this summary: 16 May 2008

(2) Device trade or proprietary name: Glucose Meter-Check™ Control Solution for Roche ACCU-CHEK

Device common or usual name or classification name:

75 JJX, single (specified) analyte controls (assayed and unassayed)

	CLASSIFICATION		
PRODUCT NOMENCLATURE	**NUMBER**	**CLASS**	**PANEL**
SINGLE ANALYTE CONTROL SOLUTION	862.1660	I	75 CLINICAL CHEMISTRY

I. Substantial Equivalence

Glucose Meter-Check™ Solution is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use:

Comparison of Glucose Meter-Check™ Control Solution to predicate devices for substantial equivalency

Product	Glucose Meter-Chek Solution	Accu-Chek AVIVA Control		Accu-Chek ACTIVE Control		Accu-Chek ADVANTAGE Control		Accu-Chek COMPACT Control		SMS Glucose Control
		K043474		K012324		K032552		K022171		K070506
S10(k), Date		04.27.05		12.05.01		09.12.03		07.23.02		04.18.07
Net Fill	4 mL	2.5 mL		4 mL		4 mL		3 mL		3.6 mL
Color	red	blue		clear		blue		dark blue		red
Analyte	glucose	glucose		glucose		glucose		glucose		glucose
Container	plastic vial	plastic vial		plastic vial		plastic vial		plastic vial		plastic vial
Matrix	aqueous	aqueous		aqueous		aqueous		aqueous		aqueous
Level	normal	low	high	low	high	low	high	low	high	normal
Mid Assigned Range*	107	40	300	54	173	61	342	83	410	169

*Mid Assigned Range is mean of assigned ranges for each meter (Accu-Chek ACTIVE for Glucose Meter-Check and SMS Glucose Control)

[2] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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II. **Description of the new device**

Glucose Meter-Check™ Control Solution is a single-level, viscosity-adjusted, aqueous liquid glucose control solution. **Glucose Meter-Check™ Control Solution** is intended for use to verify the performance of the Roche ACCU-CHEK brand BGM Systems listed in the package insert at glucose levels within the normal fasting blood glucose range for non-diabetic persons. This mid-level glucose concentration will complement the current, low and high glucose concentrations available in quality control products distributed by Roche Diagnostics for these same BGM systems. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.

Glucose Meter-Check™ Control Solution is a non-hazardous aqueous solution containing no human or animal-derived materials.

(5) **Intended use of the device**

Glucose Meter-Check™ Control Solution is intended for in vitro diagnostic use to assess the performance of the Roche ACCU-CHEK blood glucose test systems: Aviva, Active, Advantage and Compact and Compact Plus by healthcare professionals and in the home by people with diabetes mellitus.

(6) **Technological characteristics of the device.**

This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a single concentration of D-glucose and has been optimized to simulate the response of whole blood on the Roche ACCU-CHEK blood glucose test systems. The solution contains no hazardous, human or animal derived components.

(b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability
b) Stability after opening
c) Bias to glucose as determined by YSI 2300
d) Test precision and range

(b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**

N/A

(b) (3) **Conclusions drawn from the clinical and non-clinical trials.**

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bionostics, Inc.
c/o Mr. Randy Byrd
Vice President, Chief Technical Officer
7 Jackson Road
Devens, MA 01432

JUL 2 5 2008

Re: k081403
Trade Name: Glucose Meter-Check™ Control Solution for Roche ACCU-CHEK
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: July 15, 2008
Received: July 16, 2008

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): **K081403**

Device Name: **Glucose Meter-Check™ Control Solution for Roche ACCU-CHEK**

Indication For Use:

Glucose Meter-Check™ Solution is intended to assess the performance of the following Roche ACCU-CHEK blood glucose test systems:

- Roche ACCU-CHEK Advantage using Comfort Curve® test strips
- Roche ACCU-CHEK Active®
- Roche ACCU-CHEK Aviva®
- Roche ACCU-CHEK Compact® and ACCU-CHEK Compact Plus®

The Meter-Check Glucose Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ✓ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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